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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,453	08/18/2006	Gina Fischer	028232-0113	3166

22428 7590 08/05/2010

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
08/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,453	FISCHER ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-66 and 69-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-66 and 69-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and claims filed (after mailing of the final rejection) on 07/12/10 are acknowledged.

2. Claims 1-63 and 67-68 were cancelled.

3. Claims 64-66 and 69-81 are included in the prosecution.

4. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

Rejection of claims under 35 USC § 112, 2nd paragraph

5. In light of the cancellation of claims 67 (and dependent claim 68), the rejection of these claims under 35 USC § 112, second paragraph is withdrawn.

Rejection of claims under 35 USC § 102(e)

6. Applicant's arguments, see Page 5, filed 07/12/10, with respect to the rejection of claims 64-68 and 76-81 under 35 USC § 102(e) as being anticipated by Fischer et al. (US 2004/0253310 A1) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Rejection of claims under 35 USC § 103(a)

7. Applicant's arguments, see Page 6, filed 07/12/10, with respect to the rejection of claims 69-75 under 35 USC § 103(a) as being unpatentable over Fischer et al. (US 2004/0253310 A1) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Rejection of claims under Obviousness-type Double Patenting

8. Applicant's arguments, see Page 6, filed 07/12/10, with respect to the provisional rejection of claims 64-81 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 3-47, and 49-71 of co-pending Application No. 10/550,685 and the provisional rejection of claims 64-81 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 60-100 of co-pending Application No. 12/078,312 have been fully considered and are persuasive. Therefore, the rejections have been withdrawn.

New ground(s) of rejection

9. Upon further consideration, new ground(s) of rejection follow.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 64 and dependent claims 65-66 and 69-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 64 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** Claim 64 (line 9) was amended to delete the term "substantially" regarding the matrix composition.

After carefully examining the instant disclosure, the examiner respectfully submits that support for this amendment is lacking and the deletion of the term "substantially" is new matter. Although the limitation: "substantially insoluble" is disclosed in the instant specification (Page 7, line 6, Page 10, line 34, Page 12, line 2, Page 32, lines 28-32), the limitation of a completely "insoluble" coating is not disclosed. This limitation of an "insoluble" coating was not set forth and is considered new matter. Dependent claims 65-66 and 69-81 are also rejected because they depend on claims that recite the phrase "insoluble" with reference to the coating, which is new matter.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 64 and dependent claims 65-66 and 69-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 64 recites "wherein the matrix composition does not comprise a surface active agent". However, the polymers that are the components of the matrix composition include "polyethylene glycol" which is a known surfactant. It is unclear how a limitation excluding a surfactant can allow the presence of a surfactant.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 64-66 and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al. (US 2003/0203055 A1).

Rao teaches a method of treating visceral pain (Abstract) and discloses an opioid agonist and morphine (Page 9, [0137]). The active ingredient can be administered orally in solid dosage forms, such as capsules and tablets (Page 12, [0201]). Example 6 discloses a sustained release dosage form containing the active ingredient surrounded by an interior and an exterior wall, with an exit that allows for administration of the active ingredient to a patient (Page 19, [0272]). The sustained release dosage form can include the active ingredient and a polyethylene oxide carrier, which is coated with a wall comprising ethylcellulose (Page 19, [0273]). The sustained release dosage form can also include the active ingredient and a polyethylene oxide carrier, which is coated with an interior wall comprising ethyl cellulose and an exterior wall containing cellulose acetate (Page 19, [0274]). The water insoluble, water impermeable polymeric coating can contain cellulose acetate, ethylcellulose or polyvinyl chloride; and the coating of the tablet can have apertures exposing the core (Page 20, [0285]).

Rao does not expressly teach an example with an opioid in the controlled release polymer matrix that is coated with an insoluble or impermeable coating with apertures.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of treating pain by using an opioid in the sustained release dosage form containing the active ingredient surrounded by a wall, with an exit that allows for administration of the active ingredient to a patient, as suggested by Rao, and produce the instant invention.

One of ordinary skill in the art would do this because analgesics such as opioids are used in the method of treating, as suggested by Rao. It is obvious to substitute one known element (analgesics for pain) for another (opioid for pain) and obtain predictable results. Please see MPEP 2141.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 64, the method of treating a patient suffering from pain that is sensitive to an opioid comprising orally administering such opioid in a controlled release pharmaceutical composition would have been obvious over the method of treating visceral pain (Abstract) by using an opioid agonist or morphine (Page 9, [0137]), as taught by Rao. The limitations of the pharmaceutical composition comprising a matrix comprising polymer(s) and an opioid would have been obvious over the opioid and morphine (Page 9, [0137]) that may be used in the matrix along with a polyethylene oxide carrier (Page 19, [0273]) as taught by Rao. The limitation of the matrix composition not comprising a surface active agent is obvious over the matrix compositions taught by Rao (Page 19, [0273]). The limitation of the coating that is insoluble in and impermeable to aqueous media is obvious over the wall comprising ethyl cellulose and cellulose acetate (Page 19, [0274]), as taught by Rao. The limitation of the coating having at least one opening exposing at least one surface of the matrix is

obvious over the coating of the tablet that can have apertures exposing the core (Page 20, [0285]) as taught by Rao.

Regarding instant claims 65-66, the limitations of the amount of opioid would have been obvious over the method of treating pain (Abstract) by using an opioid agonist or morphine (Page 9, [0137]), as taught by Rao. One of ordinary skill in the art would find it obvious to compare the sustained opioid release with an immediate opioid release in order to determine an efficacious pain treatment regimen. The limitation of measuring the degree of pain would have been obvious as a quantifiable measure of pain treatment that is part of routine experimentation.

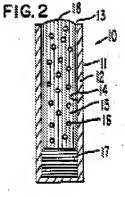
Regarding instant claim 79, the limitation of chronic pain would have been obvious over the chronic inflammatory pain taught by Rao (Page 3, [0029]).

Regarding instant claims 80-81, the limitation of the polyglycol in the polymer matrix would have been obvious over the polyethylene glycol (Page 12, [0210]) and the polyethylene oxide carrier (Page 19, [0273] - [0274]) taught by Rao.

17. Claims 64-66 and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (US 4,824,675) in view of Rao et al. (US 2003/0203055 A1).

Wong teaches an orally administrable delivery dispenser that contains a drug core with a cellulose acetate wall, a matrix containing tiny pills of the drug and polyethylene oxide, and a mouth in the outer wall (Example 7, Col. 22, line 30 to Col. 23, line 22). The wall forming materials include cellulose acetate (Col. 8, line 39) –

which is substantially impermeable to the passage of the drug (Col. 15, lines 32-34), ethyl cellulose (Col. 8, line 64), polyamides (Col. 9, line 1), ethylene-vinyl acetate, polyethylene, ethyl cellulose, and polypropylene (Col. 15, lines 55-63). Matrix components such as polyethylene oxide (Col. 11, lines 28-29), polyglycolic acid (Col. 13, lines 42-43), polylactic acid (Col. 13, line 45) and polylactideglycolide (Col. 13, line 49) are disclosed. The active drug can be an analgesic (Col. 16, lines 46-48). The following illustrates the arrangement of the inner lumen (14) (or polymeric matrix with the tiny drug-containing pills), the outer wall (12) and the mouth or opening (13).



Wong does not expressly teach an opioid.

The teaching of Rao is stated above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the orally administrable delivery dispenser that contains a matrix containing polyethylene oxide and tiny pills of a drug, where the matrix is surrounded by a cellulose acetate wall, and there is a mouth in the wall, for delivering an analgesic, as taught by Wong, use an opioid as the analgesic in a sustained release dosage form containing the active ingredient surrounded by a wall, with an exit that

allows for administration of the active ingredient to a patient, as suggested by Rao, and produce the instant invention.

One of ordinary skill in the art would do this because both Wong and Rao teach the delivery of an analgesic from a sustained release delivery device that contains an inner matrix comprising a polymer and the active, a wall surrounding the matrix formed of impermeable materials, and having an opening or exit in the wall. One of ordinary skill in the art knows that analgesics are used in the method of treating pain and that opioids are used for treating pain, as evidenced by Rao. It is obvious to substitute one known element (analgesics for pain – taught by Wong) for another (opioid for pain – taught by Rao) and obtain predictable results. Please see MPEP 2141.

Regarding instant claim 64, the method of treating a patient suffering from pain that is sensitive to an opioid comprising orally administering such opioid in a controlled release pharmaceutical composition would have been obvious over the orally administrable delivery dispenser that contains a drug core (Example 7, Col. 22, line 30 to Col. 23, line 22) and where the drug can be an analgesic (Col. 16, lines 46-48) as taught by Wong in view of the method of treating visceral pain (Abstract) by using an opioid agonist or morphine (Page 9, [0137]), as taught by Rao. The limitations of the pharmaceutical composition comprising a matrix comprising polymer(s) and an opioid would have been obvious over the delivery dispenser that contains a matrix containing tiny pills of the drug and polyethylene oxide (Example 7, Col. 22, line 30 to Col. 23, line 22) as taught by Wong, in view of the opioid and morphine (Page 9, [0137]) that may be used in the matrix along with a polyethylene oxide carrier (Page 19, [0273]) as taught by

Rao. The limitation of the matrix composition not comprising a surface active agent is obvious over the matrix compositions taught by Wong (Col. 22, Example 7) and Rao (Page 19, [0273]). The limitation of the coating that is insoluble in and impermeable to aqueous media is obvious over the wall forming materials including cellulose acetate (Col. 8, line 39) – which is substantially impermeable to the passage of the drug (Col. 15, lines 32-34), ethyl cellulose (Col. 8, line 64), polyamides (Col. 9, line 1), ethylene-vinyl acetate, polyethylene, ethyl cellulose, and polypropylene (Col. 15, lines 55-63), as taught by Wong and by the wall comprising ethyl cellulose and cellulose acetate (Page 19, [0274]), as taught by Rao. The limitation of the coating having at least one opening exposing at least one surface of the matrix is obvious over the mouth in the outer wall (Example 7, Col. 22, line 30 to Col. 23, line 22 and Fig. 2) as taught by Wong and over the coating of the tablet that can have apertures exposing the core (Page 20, [0285]) as taught by Rao.

Regarding instant claims 65-66, the limitations of the amount of opioid would have been obvious over the method of treating pain (Abstract) by using an opioid agonist or morphine (Page 9, [0137]), as taught by Rao. One of ordinary skill in the art would find it obvious to compare the sustained opioid release with an immediate opioid release in order to determine an efficacious pain treatment regimen. The limitation of measuring the degree of pain would have been obvious as a quantifiable measure of pain treatment that is part of routine experimentation.

Regarding instant claim 79, the limitation of chronic pain would have been obvious over the chronic inflammatory pain taught by Rao (Page 3, [0029]).

Regarding instant claims 80-81, the limitation of the polyglycol in the polymer matrix would have been obvious over the matrix components such as polyethylene oxide (Col. 11, lines 28-29), polyglycolic acid (Col. 13, lines 42-43), polylactic acid (Col. 13, line 45) and polylactideglycolide (Col. 13, line 49) taught by Wong and over the polyethylene glycol (Page 12, [0210]) and the polyethylene oxide carrier (Page 19, [0273] - [0274]) taught by Rao.

18. Claims 64-66 and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over DePrince et al. (US 4,898,733) in view of Rao et al. (US 2003/0203055 A1).

DePrince teaches a method of administering a beneficial agent through oral ingestion of a device (Col. 2, lines 30-34). The beneficial agent can be an analgesic drug (Col. 4, lines 31-40). The device is a compression molded tablet comprising at least two layers; a non-body fluid contacting layer which is sandwiched between two-body fluid-contacting layers, and the device is partially overlaid with an impermeable coating (Col. 2, lines 35-45, lines 54-64, and Figures 1-2).

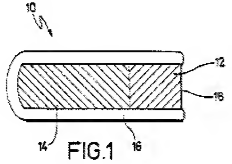
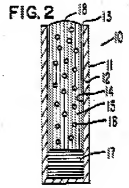


FIG.1

The polymeric material used to form the matrix includes polyethylene glycol (Col. 5, lines 28-35). The tablet is partially coated with a coating material that is impermeable to body fluids and to the beneficial agent and substantially insoluble in body fluids, the sleeve (or coating) may be open at one end, and suitable sleeve materials include cellulose acetate, polyvinyl acetate, polyurethane, polyamide and ethylene-vinyl acetate (Col. 5, line 44 to Col. 6, line 13). The device may then be orally ingested for the continuous administration of the beneficial drug (Col. 6, lines 13-16).



DePrince does not expressly teach an opioid.

The teaching of Rao is stated above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the orally ingestible device that contains a matrix containing polyethylene glycol and a drug such as an analgesic, where the matrix is surrounded by a coating that is substantially insoluble and impermeable comprising coating materials, and with an opening in the coating, as taught by DePrince, use an opioid as the analgesic in a sustained release dosage form containing the active ingredient

surrounded by a wall, with an exit that allows for administration of the active ingredient to a patient, as suggested by Rao, and produce the instant invention.

One of ordinary skill in the art would do this because both DePrince and Rao teach the delivery of an analgesic from a sustained release delivery device that contains an inner matrix comprising a polymer and the active, a wall surrounding the matrix formed of impermeable materials, and having an opening or exit in the wall. One of ordinary skill in the art knows that analgesics are used in the method of treating pain and that opioids are used for treating pain, as evidenced by Rao. It is obvious to substitute one known element (analgesics for pain – taught by Wong) for another (opioid for pain – taught by Rao) and obtain predictable results. Please see MPEP 2141.

Regarding instant claim 64, the method of treating a patient suffering from pain that is sensitive to an opioid comprising orally administering such opioid in a controlled release pharmaceutical composition would have been obvious over the orally ingestible device comprising a beneficial drug such as an analgesic overlaid with an impermeable coating (Col. 2, lines 35-45, lines 54-64, and Figures 1-2) as taught by DePrince, in view of the method of treating pain (Abstract) by using an opioid agonist or morphine (Page 9, [0137]), as taught by Rao. The limitations of the pharmaceutical composition comprising a matrix comprising polymer(s) and an opioid would have been obvious over the delivery dispenser that contains a matrix containing the drug and polyethylene glycol (Col. 5, lines 28-35) as taught by DePrince, in view of the opioid and morphine (Page 9, [0137]) that may be used in the matrix along with a polyethylene oxide carrier (Page 19,

[0273]) as taught by Rao. The limitation of the matrix composition not comprising a surface active agent is obvious over the matrix compositions taught by DePrince (Col. 5, lines 28-35) and Rao (Page 19, [0273]). The limitation of the coating that is insoluble in and impermeable to aqueous media is obvious over the wall forming materials including cellulose acetate, polyvinyl acetate, polyurethane, polyamide and ethylene-vinyl acetate (Col. 5, line 44 to Col. 6, line 13) taught by DePrince and by the wall comprising ethyl cellulose and cellulose acetate (Page 19, [0274]), as taught by Rao. The limitation of the coating having at least one opening exposing at least one surface of the matrix is obvious over the sleeve (or coating) that may be open at one end (Col. 5, lines 62-67) and over the coating of the tablet that can have apertures exposing the core (Page 20, [0285]) as taught by Rao.

Regarding instant claims 65-66, the limitations of the amount of opioid would have been obvious over the method of treating pain (Abstract) by using an opioid agonist or morphine (Page 9, [0137]), as taught by Rao. One of ordinary skill in the art would find it obvious to compare the sustained opioid release with an immediate opioid release in order to determine an efficacious pain treatment regimen. The limitation of measuring the degree of pain would have been obvious as a quantifiable measure of pain treatment that is part of routine experimentation.

Regarding instant claim 79, the limitation of chronic pain would have been obvious over the chronic inflammatory pain taught by Rao (Page 3, [0029]).

Regarding instant claims 80-81, the limitation of the polyglycol in the polymer matrix would have been obvious over the polyethylene glycol used to form the matrix

(Col. 5, lines 28-35) as taught by DePrince and over the polyethylene glycol (Page 12, [0210]) and the polyethylene oxide carrier (Page 19, [0273] - [0274]) taught by Rao.

19. Claims 69-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al. (US 2003/0203055 A1) in view of Sackler et al. (US 5,478,577).

The teaching of Rao is stated above.

Rao does not expressly teach the mean plasma concentration of the opioid or a once daily administration of the opioid.

Sackler teaches a method for providing effective pain management in humans for a time period of about 24 hours, comprising preparing a solid, controlled-release oral dosage form by incorporating an analgesically effective amount of an opioid analgesic into a controlled release dosage form which provides a rapid rate of initial rise of the plasma concentration of the opioid such that the peak plasma level of the opioid analgesic obtained in-vivo occurs from about 2 to about 8 hours after administration of the dosage form (Col. 4, lines 3-14). Sackler teaches that the oral opioid analgesics have been formulated to provide for an increased duration of analgesic action allowing once-daily dosing (Col. 7, lines 52-54). Morphine sulfate is used at 30mg dosage (Col. 13, line 44 to Col. 14, line 8, Table 1, Examples 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use an opioid as the analgesic in a sustained release dosage form containing the active ingredient surrounded by a wall, with an exit that allows for administration of the active ingredient to a patient, as suggested by Rao, in view of the

oral once daily administration of an opioid with a plasma concentration of the opioid such that the peak plasma level of the opioid obtained in-vivo occurs from about 2 to about 8 hours after administration of the dosage form, as suggested by Sackler, and produce the instant invention.

One of ordinary skill in the art would do this because determination of the plasma concentration of the opioid formulation is part of routine experimentation when orally administering opioids for the treatment of pain.

Regarding claims 69-75, the recitations of the plasma concentration over various time periods would have been obvious variants over the sustained release orally administrable dosage forms taught by Rao (Page 19, [0272] – [0274]), and Sackler (Col. 7, lines 52-54) and the plasma concentrations taught by Sackler (Col. 4, lines 3-14) unless there is evidence of criticality or unexpected results.

Regarding claims 76-77, the limitation of once daily administration of the composition would have been obvious over the once-daily dosing taught by Sackler (Col. 7, lines 52-54).

Regarding claim 78, the limitation of 15 to 300 mg of morphine sulphate would have been obvious over the morphine sulfate used at 30mg dosage as taught by Sackler (Col. 13, line 44 to Col. 14, line 8, Table 1, Examples 1-2).

Art of Interest

20. The following references are cited as art of interest for teaching orally administrable dosage forms containing matrices with active ingredients, surrounded

partially by impermeable outer layers or coatings of that contain polyvinyl chloride,

polyurethanes, polyamides, cellulose acetate.

- Bar-Shalom et al. (US 5,618,560)
- Babich et al. (US 6,395,299 B1)
- Am Ende et al. (US 6,517,866 B1)
- Sowden et al. (US 2004/0213849 A1)

Conclusion

21. Due to the new grounds of rejection, this action is made non-final.

22. No claims are allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615